IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO

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| MARK GILBERT RIMBERT, individually and as Personal Representative of the Estates of GILBERT JOHN RIMBERT, and OLIVIA ACOSTA RIMBERT, deceased, Plaintiff, | § | |
| vs. | § | CASE #1:06-cv-00874-JB-LFG |
| ELI LILLY AND COMPANY, Defendant. | § | |

**PLAINTIFF'S REPLY TO DEFENDANT'S RESPONSE TO NOTICE OF SUPPLEMENTAL AUTHORITY, AND NOTICE OF FURTHER SUPPLEMENTAL AUTHORITY**

Confirming Plaintiff's assertion that the Supreme Court has resolved the preemption issue in this case in *Wyeth v. Levine*, the United States District Court for the District of Wyoming found *Levine* dispositive in an antidepressant/suicide case last week. Plaintiff has attached a copy of the order in *Van Dyke v. GlaxoSmithKline, et al.*, Cause No. 05-CV-153-J (March 27, 2009).

In *Levine*, the Supreme Court held that "it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times." *Levine* at 14. As the Court emphasized, drug manufacturers have the power and the duty under the federal regulations to add warnings when appropriate, without prior FDA approval. A conflict in this situation could only arise when there is "clear evidence" that FDA would have rejected the added warning. *Id*. at 15.

Prior to the month that Gilbert Rimbert obtained his first prescription for Prozac, no antidepressant manufacturer had ever proposed or added a warning of the association between antidepressants and increased suicidal thoughts or behavior. On two occasions – in August 2003 and

in May 2006 – antidepressant manufacturers actually added warnings without prior FDA approval. In neither instance did FDA "reject" the added warning or pursue misbranding. To the contrary, FDA allowed the warnings to stand for seven months and a full year, respectively, until it began to require additional class-wide warnings for all antidepressants. To this day, FDA has never rejected any added warning of increased suicidality proposed by any antidepressant manufacturer.

Six months after Gilbert Rimbert's suicide, moreover, FDA issued a Public Health Advisory, warning of increased suicidality associated with antidepressants in both pediatric and adult patients. Another Public Health Advisory of this association followed in June 2005.

The evidence in this case is indeed clear. Eli Lilly never proposed or added a warning of increased suicidality prior to the prescription of Prozac to Gilbert Rimbert, and FDA would not have rejected any such warning if it had done so. According to the standard set forth in *Levine*, there is no conflict whatsoever in this case that could support preemption.

Respectfully submitted,

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Certificate of Service

I certify that on this 30th day of March, 2009, Plaintiff's Reply to Defendant's Response to Notice of Supplemental Authority, and Notice of Further Supplemental Authority has been electronically filed with the Clerk using the CM/ECF system, which will automatically send email notifications of such filing to the following attorneys of record:

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